

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO WAVE 1 CASES ON ATTACHED EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF
DEFENSE EXPERT ELIZABETH KAVALER**

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PRELIMINARY STATEMENT

Dr. Elizabeth Kavaler is a urologist. Dr. Kavaler's general reports set forth opinions on all liability issues, including design defect and failure to warn, with regard to the Prolift, TVT, and TVT-O. However, Dr. Kavaler has no experience with the design of a mesh device, study or teaching of warnings, and has admitted to a lack of foundational knowledge. Most glaring, she admits that her opinions of adequacy are based on her own subjective practice and needs, without reference to any objective standards or criteria.

Dr. Kavaler applies no objective standards or criteria in forming her opinions, and thus follows no scientific methodology. Her opinions lack foundation, and have no general applicability. The opinions therefore fail to satisfy Daubert and should be precluded.

LEGAL ARGUMENT

I.

DR. KAVALER'S GENERAL OPINIONS SHOULD BE PRECLUDED OR LIMITED

Dr. Kavaler's opinions are based solely on her clinical practice and experience, without reference to the literature or other people's experiences. (Dr. Kavaler 12/4/12 Dep. Tr., 123:19-24; Exhibit B). Dr. Kavaler's opinions on the warnings are classic net opinions, with no applicability to anyone but her, since they are based solely on what is adequate for her in her own practice, without reference to any standards or criteria; in fact she did not even consider Ethicon's own standards or conduct, thus there is no objective basis for any of her opinions. (Dr. Kavaler 12/4/12 Dep. Tr., 64:10-66:5; Exhibit B). Dr. Kavaler also has a huge gap in her reliance base, as she has looked at no internal Ethicon documents, and has not reviewed or relied on deposition testimony of any Ethicon witness. (Dr. Kavaler 10/14/14 Dep. Tr., 46:2-19; Exhibit D). She essentially knows nothing about the majority of the evidence and testimony that will be presented to the jury at trial.

Beyond the systemic lack of a reliable basis or methodology for her opinions, Dr. Kavaler admitted that she has no opinion, or has no foundation to support an opinion, on central issues, including but not limited to:

Failure to Warn

1. Any opinion Dr. Kavaler might have on the IFU is based solely on her own personal perspective. (Dr. Kavaler 10/14/14 Dep. Tr., 53:18-22; Exhibit D).
2. Dr. Kavaler does not have "much of an opinion on the IFU." (Dr. Kavaler 10/14/14 Dep. Tr.; 57:18-58:9; Exhibit D).

3. Dr. Kavaler has **no opinion** on Ethicon's warning obligations in the IFU. (Dr. Kavaler 10/14/14 Dep. Tr., 63:20-64:17; Exhibit D).

4. Dr. Kavaler **does not know the purpose of the IFU** from Ethicon's perspective. (Dr. Kavaler 10/14/14 Dep. Tr., 52:4-7; 52:17-24; Dr. Kavaler).

5. Dr. Kavaler **does not know** what the FDA regulations require with regard to the IFU, or what Ethicon's obligations were. (Dr. Kavaler 10/14/14 Dep. Tr., 53:2-16; 62:20-64:11; Exhibit D).

6. Dr. Kavaler could not say, and has **no opinion**, as to whether claims in the IFU should be supported by data. (Dr. Kavaler 10/14/14 Dep. Tr., 61:8-24; Exhibit D).

7. Dr. Kavaler has **no opinion** whether Ethicon was obligated to list the known risks and complications in the IFU. (Dr. Kavaler 10/14/14 Dep. Tr., 63:20-64:17; Exhibit D).

8. Dr. Kavaler has **no opinion** as to whether the information in the IFU should be truthful, because, "I don't put this much thought into the IFU." (Dr. Kavaler 10/14/14 Dep. Tr., 57:18-58:4; Exhibit D).

9. Dr. Kavaler did not use the patient brochure, and has **no opinion** on it. (Dr. Kavaler 10/14/14 Dep. Tr., 65:9-65:19; 66:1-19; Exhibit D).

10. Dr. Kavaler **does not know** any standards or criteria for what needed to be in the patient brochure. (Dr. Kavaler 10/14/14 Dep. Tr., 70:25-71:12; Exhibit D).

Design Defect

11. Dr. Kavaler has no opinion as to whether, "a medical device manufacturer has the obligation to research the safety of its products before putting them on the market." (Dr. Kavaler 4/8/14 Dep. Tr., 21:1-15; Exhibit C).

12. Dr. Kavaler does not know the design intent for the Prolift. (Dr. Kavaler 12/4/12 Dep. Tr., 70:14-24; Exhibit B).

13. Dr. Kavaler has no opinions as to whether Ethicon met its own internal procedures or criteria for whether the Prolift should have been marketed. (Dr. Kavaler 10/14/14 Dep. Tr., 49:21-50:3; Exhibit D).

14. Dr. Kavaler has not looked at the question of whether the pores of the mesh collapse in the body. (Dr. Kavaler 10/14/14 Dep. Tr., 95:1-7; Exhibit D).

15. Dr. Kavaler does not know whether Ethicon was studying the issue of whether the pores of the mesh collapse inside the body. (Dr. Kavaler 10/14/14 Dep. Tr., 95:8-96:2; Exhibit D).

16. Dr. Kavaler has never studied pore sizes after explant. (Dr. Kavaler 10/14/14 Dep. Tr., 96:3-14; Exhibit D).

This Court has previously precluded or limited expert opinions where experts have similarly admitted to an inadequate basis, and failure to apply objective standards, in offering general opinions. For example, in precluding the warning opinions of Ethicon defense expert Denise Elser, in the Bellew case, the Court found:

Dr. Elser's familiarity with IFU's comes solely from her clinical practice... (Q: You're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair? A: That's fair."). In fact, she admits that she did not even know that there were regulations governing what information must be provided in the IFU.

Bellew v. Ethicon, et al., No. 2:13-cv-22473 at 33, (S.D. W.Va. Nov. 20, 2014) [Document 265].

In precluding the warning opinions of Ethicon's other failure to warn expert in the Bellew case, Dr. Christina Pramudji, this Court focused as well on the expert's admission that she did not rely on any FDA or internal Ethicon standards in offering her opinions. Id. at 36.

Dr. Kavaler's deposition testimony demonstrates that she has no objective opinions, and in fact applied no standards in forming the opinions that she does have. The failure to take into account an objective standard, not even the standards Ethicon agreed were applicable, is fatal to these opinions. This Court's ruling in the Bellew case applies with equal or stronger force here, where the testimony goes even further in establishing the expert's lack of qualification or foundation to give her general opinions on warnings and design defect, to the extent she actually holds such an opinion. Thus, the opinions are precluded under Daubert.

CONCLUSION

For all of the foregoing reasons, Plaintiff's Daubert motion to preclude or limit the opinions of Dr. Kavaler should be granted.

Respectfully submitted,

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